

REMARKS

Applicants thank the Examiner for the detailed Office Action dated 25 October 2006. Applicants respectfully request reconsideration of the present application in view of the reasons that follow.

Claims 1-40 and 42-46 were previously pending in the application. Claims 34-36 are requested to be cancelled without prejudice or disclaimer. Claims 1-9, 11-15, 19-21, 23, 25, 28-31, 37, 42-43, and 45 are currently being amended. Claims 47-52 are being added. After amending the claims as set forth above, claims 1-33, 37-40, and 42-52 are now pending in this application.

For simplicity and clarity purposes in responding to the Office Action, Applicants' remarks are primarily focused on the rejections of the independent claims (*i.e.*, claims 1, 15, 25, 28, 31, 37, 41, and 42) outlined in the Office Action with the understanding that the claims that depend from the independent claims are patentable for at least the same reasons (and in most cases other reasons) that the independent claims are patentable. Applicants expressly reserve the right to argue the patentability of the dependent claims separately in any future proceedings.

Claim Rejections – 35 U.S.C. § 112 ¶2

On pages 2 and 5 of the Office Action, claims 1-14, 20, and 34-36 were rejected under 35 U.S.C. § 112 ¶2 as being unpatentable for failing to particularly point out and distinctly claim the subject matter which the Applicants regard as the invention. In particular, the Patent Office objected to the use of “open rectangle” in claims 1 and 34 and questioned how the filament weaves through the internal component at “approximately a middle of the external component” in claim 20. Applicants have cancelled claim 34 and removed any reference to an “open

rectangle” in claim 1. Applicants have also amended claim 20 to remove the terminology that was questioned by the Patent Office. Applicants respectfully submit that the rejected claims particularly point out and distinctly claim the subject matter in compliance with 35 U.S.C. § 112 ¶ 2. Accordingly, Applicants respectfully request that the rejection be withdrawn.

Claim Rejections – 35 U.S.C. § 102

Independent Claims 1 and 15 in view of Nash et al.

On page 3 of the Office Action, independent claims 1 and 15 and various dependent claims were rejected under 35 U.S.C. § 102(b) as being unpatentable over U.S. Patent No. 5,662,681 (Nash et al.). Applicants respectfully traverse the rejection. Nash et al. does not identically disclose the subject matter recited in independent claims 1 or 15.

Claim 1, as amended, recites, among other things, that “the filament passes from a first hole in the sealing plug to a hole in the anchor and back through a second hole in the sealing plug.” Claim 15, as amended, recites, among other things, that “the filament passes from a first hole in the external component to a hole in the internal component and back through a second hole in the external component.” The device shown in Nash et al. does not meet either of these limitations. Instead of having the filament return to the sealing plug through a second or different hole, the filament used with the device in Nash et al. passes out of and returns back through the same hole (30A in FIG. 2) in the sealing plug.

Claim 15, as amended, recites, among other things, that “the external component [is] folded between the first hole in the external component and the second hole in the external component” and “the tissue puncture sealing device is in an undeployed configuration.” The device shown in Nash et al. does not meet these limitations. Nash et al. makes it very clear that

when the device is in an undeployed configuration, the sealing plug 30 is “straightened.” See Nash et al. I, col. 5, lines 6-10.

For the above reasons, Applicants respectfully submit that independent claims 1 and 15 and the claims which are dependent thereon are not anticipated by the cited reference and are patentable.

Independent Claim 28 in view of Rousseau

On page 3 of the Office Action, independent claim 28 was rejected under 35 U.S.C. § 102(b) as being unpatentable over Rousseau. Applicants respectfully traverse the rejection. Rousseau does not identically disclose the subject matter recited in independent claim 28.

Claim 28, as amended, recites, among other things, “the flexible sealing plug including a first plurality of openings and a second plurality of openings” and that “the filament passes through at least two openings from the first plurality of openings, through the anchor, and back through at least two openings from the second plurality of openings.” The device shown in Rousseau does not meet these limitations. The filament in Rousseau only extends through a single opening in the sealing plug (the upper conical member 14 is the sealing plug according to the Patent Office’s interpretation), through the anchor (the lower conical member 14 is the anchor according to the Patent Office’s interpretation), and back through a single opening in the upper conical member 14. Thus, the filament does not pass through at least two openings in the sealing member before passing through the anchor, and the filament does not pass through at least two openings in the sealing plug after passing through the anchor (see FIG. 1 of Rousseau) as required by claim 28.

For the above reasons, Applicants respectfully submit that independent claim 28 is not anticipated by the cited reference and is patentable.

Independent Claim 43 in vie w of Thal

On page 4 of the Office Action, independent claim 43 was rejected under 35 U.S.C. § 102(b) as being unpatentable over U.S. Patent No. 5,720,765 (Thal). Applicants respectfully traverse the rejection. Thal does not identically disclose the subject matter recited in independent claim 43.

Claim 43, as amended, recites, among other things, a “sealing plug that is flexible” and “the sealing plug being configured to change shape upon being coupled to the anchor with the filament.” The stop means 54 in Thal is not explicitly disclosed as being flexible so that it can change shape upon being coupled to the anchor with the filament. In fact none of the various stop means shown in Thal are disclosed as having these attributes.

Applicants note that in cases where there is no express description of a claimed invention and the anticipation rejection is based on the doctrine of inherency. MPEP § 2112 sets forth the following basic principles regarding the doctrine of inherency that govern PTO practice:

(1) The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. In re Rijckaert, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993).

(2) “To establish inherency, the extrinsic evidence ‘must make clear that the missing descriptive matter is *necessarily* present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of

circumstances is not sufficient.” In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted).

(3) “In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.” Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original).

To the extent that the Patent Office relies on the doctrine of inherency, the Patent Office must explain why it the stop means in Thal are necessarily flexible even though Thal describes reattaching tissue (i.e., tendons or ligaments) to bone where the stop means is used to grab the tissue and pull it back into reattachment with the bone. See Thal, col. 6, lines 29-32. Such an application does not seem to lend itself well to a flexible material.

For the above reasons, Applicants respectfully submit that independent claim 43 is not anticipated by the cited reference and is patentable.

Independent Claims 15 and 34 in view of Kensey et al.

On page 4 of the Office Action, independent claims 15 and 34 and various dependent claims were rejected under 35 U.S.C. § 102(b) as being unpatentable over U.S. Patent No. 5,545,178 (Kensey et al.). Applicant has cancelled claims 34-36. Applicants respectfully traverse the rejection with respect to claim 15. Kensey et al. does not identically disclose the subject matter recited in independent claim 15.

Claim 15, as amended, recites, among other things, that “the filament passes from a first hole in the external component to a hole in the internal component and back through a second hole in the external component.” The device shown in Kensey et al. does not meet these

limitations. Instead of having the filament return to the sealing plug through a second or different hole, the filament used with the device in Kensey et al. passes out of and returns back through the same hole (50 in FIGS. 6-9) in the sealing plug.

For the above reasons, Applicants respectfully submit that independent claim 15 and the claims which are dependent thereon are not anticipated by the cited reference and are patentable.

Independent Claims 31 and 45 in view of Akerfeldt et al.

On page 5 of the Office Action, independent claims 31 and 45 and various dependent claims were rejected under 35 U.S.C. § 102(e) as being unpatentable over U.S. Patent No. 6,508,828 (Akerfeldt et al.). Applicants respectfully traverse the rejection. Akerfeldt et al. does not identically disclose the subject matter recited in independent claims 31 and 45.

Claim 31, as amended, recites, among other things, an “anchor disposed outside of the carrier tube at the first end thereof” and a “sealing plug disposed inside the carrier tube at the first end thereof” wherein the “tissue puncture closure device is in an undeployed configuration where the tissue puncture closure device is not inserted into a patient’s tissue or into an introducer in the patient’s tissue.” The device shown in Akerfeldt et al. does not meet these limitations. When the device shown in Akerfeldt et al. is in an undeployed configuration (it has not been inserted into a patient’s tissue or into an introducer as recited in the claim), the sealing plug is not in the carrier tube as required by claim 31.

Claim 45, as amended, recites, among other things, a “sealing plug that is generally V-shaped when the sealing plug is open and laid out flat.” The device shown in Akerfeldt et al. does not meet this limitation. When the sealing member in Akerfeldt et al. is open (i.e., not folded as explained in the specification) and laid out flat, it is not V-shaped. Instead, the sealing

member is circular in shape (See FIGS. 8 (side view of the first and second sealing members 2, 6) and 18 (end view of same); this shows they are round when flat).

For the above reasons, Applicants respectfully submit that independent claims 31 and 45 and the claims which are dependent thereon are not anticipated by the cited reference and are patentable.

Claim Rejections – 35 U.S.C. § 103(a)

Independent Claim 1 in view of Rousseau and Himpens et al.

On page 5 of the Office Action, independent claim 1 and various dependent claims were rejected under 35 U.S.C. § 103(a) as being unpatentable over Rousseau in view of U.S. Patent No. 5,397,331 (Himpens et al.). Applicants respectfully traverse the rejection. None of the cited references, alone or in combination, disclose, teach, or suggest the subject matter recited in independent claim 1.

Applicants respectfully submit that there is no motivation, teaching, or suggestion to combine the references in the manner asserted in the Office Action for at least three reasons. First, Rousseau teaches that one advantage of the device is that the prostheses both occludes the fascia defect 43 on the posterior side 47 and expands to fill the inner diameter of the defect in wall 44. See Rousseau, col. 3, lines 2-7; col. 6, lines 26-31; FIG. 4. There is no motivation to use the sheath from Himpens et al. because it would interfere with positioning and expanding the prostheses in the defect in wall 44. Likely for this reason, Himpens et al. shows using the sheath 23 to only position the net 13 on the inside wall of the peritoneum 26 (FIG. 9), not in the diameter of the defect.

Second, Rousseau teaches the use of the flat overlay sheet 26 to hold the prostheses in place. There is no motivation to use the sheath from Himpens et al. because the presence of the flat overlay sheet 26 would make it difficult or impossible to remove the sheath 23 once the prostheses were inside the body.

Third, Rousseau already teaches the use of the tubular structure 28 to impart additional axial rigidity to the prosthesis, thus improving the handling characteristics during insertion into the defect. There is not motivation to use the sheath from Himpens et al. because the motivation for doing so identified by the Patent Office, namely to make insertion easier, has already been addressed by Rousseau in a more efficient manner.

Applicants respectfully submit that to the extent the Patent Office disagrees, the Patent Office is required to make particular findings regarding why the skilled artisan, viewing each reference as a whole and with no knowledge of the claimed invention, would have combined the cited references in the manner asserted in the Office Action to provide the subject matter of independent claim 1 even though doing so would interfere with positioning and expanding the prosthesis in the hole in the wall 44, make the procedure much more complicated due to the necessity of removing the sheath when flat overlay sheet was in the way, and be redundant since Rousseau has already provided a way to make insertion of the prosthesis easier. In re Kotzab, 217 F.3d 1365, 1371, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000) (holding that the Patent Office must make “particular findings . . . as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed.”).

Applicants respectfully submit that the subject matter recited in independent claim 1 and the claims which are dependent thereon, considered as a whole, would not have been obvious to a person of skill in the art and are patentable. Accordingly, Applicants request that the Patent Office withdraw the rejection of these claims under 35 U.S.C. § 103(a).

Independent Claim 25 in view of Schmieding

On page 6 of the Office Action, independent claim 25 and various dependent claims were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,027,523 (Schmieding). Applicants respectfully traverse the rejection. Schmieding does not disclose, teach, or suggest the subject matter recited in independent claim 25.

Claim 25, as amended, recites, among other things, a “flexible sealing plug attached to the anchor by the filament.” Schmieding, however, discloses making the fixation device out of materials such PLLA or Delrin that are not flexible. Accordingly, Schmieding does not disclose all of the limitations recited in independent claim 25.

Applicants respectfully submit that the subject matter recited in independent claim 25 and the claims which are dependent thereon, considered as a whole, would not have been obvious to a person of skill in the art and are patentable. Accordingly, Applicants request that the Patent Office withdraw the rejection of these claims under 35 U.S.C. § 103(a).

Independent Claims 37 and 42 in view of Akerfeldt

On page 6 of the Office Action, independent claims 37 and 42 and various dependent claims were rejected under 35 U.S.C. § 103(a) as being unpatentable over Akerfeldt. Applicants respectfully traverse the rejection. Akerfeldt does not disclose, teach, or suggest the subject matter recited in independent claims 37 or 42.

Claim 37, as amended, recites, among other things, the “closure device being in an undeployed configuration before being inserted into the internal tissue puncture or an insertion sheath that extends into the internal tissue puncture where, in the undeployed configuration, the sealing plug is folded so that one portion of the sealing plug is in contact with another portion of the sealing plug.” The modification of Akerfeldt suggested in the Office Action does not meet this limitation of claim 37 because this limitation specifies that the sealing plug is folded to be in contact with another portion of the sealing plug before the closure device is inserted into the internal tissue puncture or into an insertion sheath positioned in the internal tissue puncture. In contrast, the Patent Office asserts in the Office Action that the parts 41 and 42 are folded in the insertion sheath 24. Applicants also notes that simply positioning the parts 41 and 42 next to each so they touch each other does not mean they are “folded.” Even though they may be touching, nothing has been folded because they are separate parts.

Claim 42, as amended, recites, among other things, that “the tissue puncture closure device is in an undeployed configuration where the tissue puncture closure device is not inserted into a patient’s tissue or into an introducer in the patient’s tissue.” The device of Akerfeldt as modified in the manner asserted by the Patent Office does not meet this limitation for the same reasons explained in connection with claim 37.

Applicants respectfully submit that the subject matter recited in independent claims 37 and 42 and the claims which are dependent thereon, considered as a whole, would not have been obvious to a person of skill in the art and are patentable. Accordingly, Applicants request that the Patent Office withdraw the rejection of these claims under 35 U.S.C. § 103(a).

New Claims

Applicants have added new claims 47-52, of which claim 47 is in independent format. These new claims more comprehensively, in combination with other existing and future claims, recite the claimed invention. Applicants submit that new claims 47-52 are patentable over the cited references.

Allowable Subject Matter

Applicants thank the Examiner for indicating that claims 23-24, 26-27, 29-30, 32, and 44 contain allowable subject matter.

Applicants respectfully put the Examiner and all others on notice that all arguments, representations, and/or amendments contained herein are only applicable to the present patent application and should not be considered when evaluating any other patent or patent application including any patents or patent applications which claim priority to this patent application and/or any patents or patent applications to which priority is claimed by this patent application.

Applicants respectfully submit that the present Application is in condition for allowance. Applicants request reconsideration and allowance of the pending claims. Applicants invite the Examiner to contact the undersigned by telephone if there remain unresolved matters to expedite the prosecution of the present application.

Respectfully submitted,

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